Application/Control Number: 10/590,348 Page 2

Art Unit: 1774

DETAILED ACTION

Allowable Subject Matter

1. Claims 18 and 20-81 are allowed.

2. The following is an examiner's statement of reasons for allowance:

Regarding claims 18 and 54 and their dependent claims, the prior art fails to disclose a device comprising a flexible sterile tube, a system of clamps dividing the tube into an upstream region, a growth chamber and a downstream region, a means of moving said clamps and a control system that measures culture density in the growth chamber and controls the means of moving said clamps based on measured culture density.

Regarding claim 30 and its dependent claims, the prior art fails to disclose a method that increases rate of reproduction of living cells through the process of natural comprising providing a sterile tube containing sterile growth medium and divided by a plurality of gates into a fresh medium chamber and a growth chamber, and inserting an initial culture in the described growth chamber through sterile injection of a starter culture into a sterile tube containing sterile growth medium; such that after a certain growth of culture density the described gates are adjusted so as to move equal portions of the sterile growth medium and of grown culture, respectively, into and out of the region defined as the growth chamber, allowing the remaining portion of the grown culture remaining in the growth chamber to mix with the introduced portion of fresh

growth medium and continue to grow whilst redefining the growth chamber until the end of experiment to achieve continuous culture and selection of variants with increased reproductive rates.

Regarding claim 35 and its dependent claims, the prior art fails to disclose a device that increases the rate of reproduction of living cells in suspension or of any culturable organisms through the process of natural selection, said device comprising:

a continuous length of flexible, sterile tubing; a system of clamps positioned at points along a section of the tubing, each of the clamps being positioned and arranged to divide the tube into separate regions when the clamps are closed such that the separate regions on respective sides of said clamp are merged back into a single region when said clamp is returned to an open position; wherein the clamps and tubing are arranged so that the tubing is clamped at first through fourth points along the tubing, defining a fresh medium chamber, a growth chamber, and a sampling chamber downstream of the first through third points, respectively; and wherein the volume of the growth chamber delimited by said points two and three is greater than a volume of the fresh medium chamber and the sampling chamber.

Regarding claim 47 and its dependent claims, the prior art fails to disclose/fairly suggest a method that increases the rate of reproduction of living cells in suspension or of any culturable organisms through the process of natural selection, wherein said method comprises steps of: providing a continuous length of flexible, sterile tubing and a

system of clamps positioned at points along a section of the tubing, closing the clamps at first through fourth points along the tubing to define first through third regions downstream of the first through third points, respectively, wherein the volume of the second region is greater than a volume of the first and third regions; and allowing the culture to grow in the culture medium in the second region; and repeating a step that comprises clamping the tubing upstream of the first point, clamping the tubing at a point between the second and third points, and returning the second point to the open position, thereby subdividing the second region into an upstream portion and a downstream portion, merging the first region and the upstream portion, and thereby defining new first through fourth points and first through third regions.

Regarding claim 65 and its dependent claims, the prior art fails to disclose a method for growing cells in continuous manner, comprising: providing a flexible tubing and a system of clamps, each of the clamps being positioned so as to be able to divide the tubing into separate regions and a control system that controls operation of the clamps such that the control system measures culture density in the growth chamber, and controls the system of clamps based on the measured culture density.

The closely related prior art to the applicants claimed invention are Okazaki (JP 03-030655) and Bieri (CH552063)

Okazaki discloses a device/system that increases the rate of reproduction (see fig 1) comprising: a flexible sterile tube (1) containing culture medium; a system of clamps (called cock 2)), each capable of open and closed positions, the clamps being positioned so as to be able to divide the tubing into separate regions containing spent culture (cultured fermenter (6)), growing culture (new fermenter (7)), and fresh growth medium (unused fermenter), and a means of moving the clamps and the tubing such that a portion of the growth chamber and the associated culture can be clamped off and separated from the growth chamber, and such that a portion of fresh tubing containing unused medium can be joined with a portion of the culture and associated medium already present in the growth chamber, wherein each of the clamps does not move with respect to the tube when said clamp is in the closed position (see fig 1 and 2, and entire document).

Bieri discloses a device that increases the rate of reproduction (see fig 3 and 4) comprising: a flexible sterile tube (3) (se fig 3 and 4) containing culture medium (1); a system of clamps (called pinchcock(6)), each capable of open and closed positions, the clamps being positioned so as to be able to divide the tubing into separate regions (see fig 3 and 4) containing spent culture, growing culture, and fresh growth medium, and a means of moving the clamps and the tubing such that a portion of the growth chamber and the associated culture can be clamped off and separated from the growth chamber, and such that a portion of fresh tubing containing unused medium can be joined with a portion of the culture and associated medium already present in the growth, wherein

each of the clamps does not move with respect to the tube when said clamp is in the closed position (see fig 3 and 4, and entire document).

Both of the references above fail to disclose a device/method of increasing the rate of reproduction comprising: a control system that controls operation of the clamps such that the control system measures culture density in the growth chamber, and controls the system of clamps based on the measured culture density. In addition, the references fail to disclose a device/method of increasing the rate of reproduction where the tubing is clamped at a first through fourth points along the tubing defining a fresh medium chamber, a growth chamber and a sampling chamber downstream of the first through third points wherein the volume of the growth chamber is greater that the fresh medium chamber and the sampling chamber. Furthermore, the references fail to disclose a method of increasing the rate of reproduction such that after a certain growth of culture density the described gates are adjusted so as to move equal portions of the fresh growth medium and of grown culture, respectively, into and out of the region defined as the growth chamber redefining the growth chamber, allowing the remaining portion of grown culture remaining in the growth chamber to mix with the introduced portion of fresh growth medium and continue to grow and redefine the growth chamber until the end of experiment to achieve continuous culture and selection of variants with increased reproductive rates.

None of the above prior arts alone or in combination discloses the applicant's claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/590,348 Page 8

Art Unit: 1774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/Walter D. Griffin/ Supervisory Patent Examiner, Art Unit 1774